Effects of Duhuojisheng Tang and combined therapies on prolapse of lumbar intervertebral disc: a systematic review of randomized control trails

Yanxu Ma, Jingyan Cui, Minghua Huang, Kai Meng, Yuhao Zhao

Abstract

OBJECTIVE: A systematic review of the literature was conducted to evaluate the curative effect and safety of Duhuojisheng Tang on prolapse of the lumbar intervertebral disc.

METHODS: The databases of PubMed, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journals Database (VIP), Chinese Biomedical Literature Database (CBM) and Chinese Medical Citation Index (CMCI) were searched up to January 30, 2012. Randomized controlled trials were selected to compare Duhuojisheng Tang with one or more of the following treatments: traction, acupuncture, massage, cupping and Western medical treatment. The quality-evaluating standard and the software RevMan 5.1 in Cochrane coordinative net were used to analyze the data. The effective indexes of the results were clinical curative rate, effectiveness of alleviating clinical symptoms and adverse reaction.

RESULTS: Thirty-one randomized controlled trials of low quality, involving 3915 patients were systematically evaluated. Statistical analyses showed that good curative effect was achieved in both the group using Duhuojisheng Tang alone and with combined therapies.

CONCLUSION: Using Duhuojisheng Tang alone or combined with other therapies can effectively improve pain, leg-raising height and other clinical symptoms of patients with prolapse of lumbar intervertebral disc. Due to low methodological quality of the articles, no exact recommendations can be made.

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Key words: Intervertebral disc displacement; Randomized controlled trials; Review; Duhuojisheng Tang

INTRODUCTION

Prolapse of lumbar intervertebral disc is a common condition, attributed to retrogression and injury of a lumbar intervertebral disc. This causes mechanical im-
The condition can be treated with or without surgery. Articles on non-surgical treatment of prolapse of lumbar intervertebral disc show that some curative effect can be achieved through one or more of the following treatments: bedrest, traction, massage, acupuncture, physical factor treatment, medicinal treatment, physiotherapy, block therapy, intervention therapy and psychological treatment. Chinese drugs commonly used to treat the condition can be divided into five types based on their intended effect: promoting blood circulation and stopping pain, nourishing the liver and kidney and strengthening the muscle and bone, promoting blood circulation and clearing collaterals, dispelling wind and dampness, and invigorating Qi. These Chinese drugs have the effects of resisting inflammation, stopping pain, regulating immune function, strengthening the phagocytic function of macrophages, improving blood supply, protecting nerves and promoting synthesis of collagen.

In recent years of clinical practice, the authors have achieved noticeable effects using Duhuojisheng Tang to treat prolapse of lumbar intervertebral disc. Duhuojisheng Tang, originating from Prescriptions Worth a Thousand Pieces of Gold for Emergencies written by Simiao Sun, a famous physician in the Tang Dynasty, consists of Duhuo (Radix Angelicae Pubescentis), Sangji (Ranunculus Ficaria), Dazhong (Cortex Eucommiae), Niuxi (Radix Atractyloides), Xixin (Herba Asari), Qinjiao (Radix Gentianae Macrophyllae), Fuling (Poria), Rouguixin (Cortex Cinnamomi), Fangfeng (Radix Lysatimii), Chuanxiong (Rhizoma Ligustici Chuanxiong), Renshen (Radix Ginseng), Gancao (Radix Glycyrrhizae), Danggui (Radix Angelicae Sinensis), Shaoysao (Radix Paeoniae), and Gandihuang (Radix Rehmanniae). With the effects of dispelling wind and dampness, stopping numbness and pain, nourishing the liver and kidney, invigorating Qi and blood, and clearing channels and collaterals, the decoction can be mainly used to treat lingering arthralgia syndrome, deficiency of both the liver and the kidney, and insufficiency of Qi and blood. Modern pharmacological researches have shown that Duhuojisheng Tang can resist inflammation, stop pain, regulate immune function, expand blood vessels and inhibit platelet aggregation. Experiments have confirmed that Duhuojisheng Tang enhances the pain threshold of mice as determined by the hot plate method, decrease the body-torsion times of mice stimulated by acetic acid and noticeably reduce the swelling of rat feet caused by adjuvant arthritis, indicating that Duhuojisheng Tang has remarkable effects of resisting inflammation and stopping pain.

The aim of this study was to evaluate the curative effects and safety of Duhuojisheng Tang on prolapse of lumbar intervertebral disc, through systematic evaluation of randomized controlled trials on the treatment of prolapse of lumbar intervertebral disc with Duhuojisheng Tang.

### METHODS

#### Inclusion criteria

In randomized controlled trials, study participants were patients with lumbar intervertebral disc prolapse diagnosed explicitly by computed tomography (CT) or magnetic resonance imaging (MRI). Intervention included Duhuojisheng Tang used alone and Duhuojisheng Tang used together with surgery, traction, acupuncture, massage, cupping or Western medical treatment. Control measures were surgery, traction, acupuncture, massage, cupping or Western medical treatment.

#### Exclusion criteria

Excluded were those experiments with Chinese drugs other than Duhuojisheng Tang to avoid confusion with its effect.

#### Retrieval and screening of articles

The five databases of PubMed, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journals Database (VIP), Chinese Biomedical Literature Database (CBM) and Chinese Medical Citation Index (CMCI) were electronically searched up to January 30, 2012 with no language limitation. The search phrases in Chinese were prolapse of lumbar intervertebral disc, Duhuojisheng Tang and randomization. The search phrases in English were Duhuosangjisheng, Radix Angelicae Pubescenti and Herba Taxilli. High-level retrieval was limited to randomized controlled trial and complementary medicine. According to various database characteristics, comprehensive retrieval was carried out by means of topic phrases combined with free phrases and key phrases, and title combined with full text. The retrieved titles and abstracts were reviewed to determine if the full text might conform to the inclusion and exclusion criteria. Those that did not meet the criteria were rejected, whereas those articles conforming to the inclusion and exclusion criteria were retained. Upon reading the articles in full, those articles not conforming to the inclusion criteria were rejected. Articles in question were compared with included and excluded articles and discussed among the authors, if necessary, to determine whether they should be included.

#### Quality evaluation

According to the method for evaluating deviation risks of randomized controlled trials in the manual for systematic evaluators in Cochran coordinative net, deviation risks were evaluated based on the following six items: the production of the order of randomized distribution, the hiding of randomized distribution, the use of blind method, the wholeness of data, whether there are reports on selection of results and other deviation sources. For each item, “yes” means low deviation, and
"no" means high risk. When inadequate information was presented in the article and we were unable to explicitly judge "yes" or "no", the item was judged as "unclear". Two researchers independently completed and mutually checked their evaluation of deviation risks. Their dispute, if any, was solved through discussion or assistance of a third researcher.

**Results indexes**

Main indexes of results were visual analog score (VAS) for pain, improvement of clinical symptoms and adverse reaction.

**Data analysis**

Contents of articles were compared and summarized. Meta-analysis was carried out with RevMan software, version 5.1 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) for systematic evaluation. Because randomized control experiments with follow-up visits were prospective, relative risk (RR) was evaluated. Cochran's Q (Chisquare test which is included the forest plots in Cochrane reviews) assesses whether observed differences in result are comparable with chance alone. The F statistic was used to quantify the percentage of variability in effect estimates that is due to heterogeneity rather than chance. If heterogeneity existed in synthetic analysis, a model of randomized effect was used. If no heterogeneity existed in synthetic analysis, a model of fixed effect was used. If heterogeneity was not large, the inclusion criteria would be deemed insufficient, and articles with low quality would be rejected or different methods of statistical analysis should be used. Furthermore, groups would be divided into subgroups to inspect the stability of the results of the Meta-analysis through sensitivity analysis.

**RESULTS**

**Characteristics of articles**

Among 251 retrieved articles were 233 articles from CNKI, 19 articles from VJCR, 25 articles from CBM, 21 articles from CMCI and 2 articles from PubMed. 165 articles were rejected on the basis of their title or abstract, and 35 full texts were finally obtained. Of these 35 articles, 31 selected articles were randomized control experiments of the treatment of prolapse of lumbar intervertebral disc with modified Duhuojiusheng Tang.

The included 31 studies involved 3915 patients suffering from prolapse of lumbar intervertebral disc diagnosed with CT or MRI. None of the studies used either comparison between Chinese medicinal treatment and a placebo treatment or blank control. Six studies compared Duhuojiusheng Tang with other therapies, and the other 25 studies compared Duhuojiusheng Tang combined with traction, acupuncture, massage or Western medical therapy with traction, acupuncture, massage or Western medical therapy. In 4 of the 31 studies, follow-up visits were paid after treatment and the remaining 27 experiments provided no information on follow-up visits. Interventional control measures, sample contents and condition of follow-up visits are shown in Table 1.

Diagnostic standards were as follows: 1. Traditional Chinese Medicine (TCM) standards for orthopedics: 1) Patients have a history of trauma to the waist, chronic strain or cold attack. 2) The disease mainly affects youth and those in their prime. 3) Lumbago radiates towards hip and lower limbs, abdominal pressure increases, pain increases during coughing and sneezing, spine laterally bends, physiological curve of lumbar vertebrae disappears, tenderness beside the vertebra at the site of pathological change radiates towards lower limbs, and lumbar activity is limited. 4) There is hyperesthesia or dyesthesia in the area controlled by affected nerves in lower limbs, and patients with long course of illness may have muscular atrophy. 5) Straight-leg-raise test or strengthening test is positive, both patellar tendon reflex and Achilles tendon reflex weaken or disappear, and backward stretching force of the thumb weakens. 6) CT examination can show the site and extent of prolapse of lumbar intervertebral disc. 2. Prolapse of lumbar intervertebral disc: 1) Pain in the waist and leg is typical for the area innervated by sciatic nerves. 2) Sensory numbness exists in the skin. 3) Straight-leg-raise test decreases by 50% as compared to the normal condition, occasionally healthy straight-leg-raise test is positive, and bow-type test can cause radiating pain proximally and distally in the limbs. 4) There are two of the four nervous signs: muscular atrophy, powerless motion, sensory reduction and reflex weakening. 5) Imaging test includes vertebral canal myelography on CT or MRI. 3. Principle for directing clinical research into new Chinese drugs: 1) Lumbago and sciatica radiate to the leg or heel, there is numbness and pain in the sole of the foot, and the straight-leg-raise test is positive. 2) There is tenderness beside the spinous process of the lumbar vertebra, and pain radiates to the lower limb, leg, foot, heel or sole. 3) The toe-stretching muscle weakens, and there is hypoesthesia in the skin on the front-outside or back-outside of the leg. 4) Roentgenogram shows no other pathological changes in lumbar vertebrae, physiological curve of lumbar vertebrae becomes straightened or intervertebral gap becomes narrowed with unequal width or hyperosteogeny at vertebral edge. 5) CT or MRI shows prolapse or bulge of intervertebral disc.

Standards for judging curative effect: curative effect was evaluated according to the TCM standard of curative effect stipulated by the National TCM Administration, principle for directing clinical research into new Chinese drugs, orthopedic standard for evaluation of curative effect, international Maenab and Watts standard, Oswestry questionnaire on indexes of dysfunction, and lumbago-evaluating scale stipulated by the orthopedic society of Japan. 1. TCM standard of curative
<table>
<thead>
<tr>
<th>Study</th>
<th>Therapeutic measure</th>
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<th>Age (year)</th>
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<tr>
<td>Li Z 2010^8</td>
<td>Duhuojisheng Tang, hot application with Chinese drug, injection of normal saline,</td>
<td>Injection of the same drugs as those in treatment group into sacral vertebral</td>
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<td>International menab and watts standard^7</td>
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<td>Injection of the same drugs as those in treatment group into sacral vertebral</td>
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<td>Illness course</td>
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<td>Liang HY 2006*1</td>
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<td>Min FJ 2003*3</td>
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<td>70-86</td>
<td>10-42 years</td>
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<td>Injection into sacral vertebral canal, compound Danshen injection and citicoline</td>
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<td>TCM standard of curative effect</td>
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</table>

Note: TCM: Traditional Chinese Medicine.
effect: "Cure" means that pain in the waist and leg disappears, straight leg can be raised by more than 70°, and the patient can return to work. "Obvious effect" means that pain in the waist and leg is completely alleviated, lumbar function is remarkably improved, and the patient can take part in heavy physical labor. "Effectiveness" means that pain in the waist and leg is alleviated, lumbar function is improved, and the patient can take part in general work. "Ineffectiveness" means that symptoms and signs are not improved. 2. International Maenab and Watts standard: "Excellent" means that symptoms and signs completely disappear, straight leg can be raised by more than 80°, muscle strength returns to normal, and the patient can return to work. "Very good" means symptoms basically disappear but mild pain and numbness remain, straight leg can be raised by more than 60°, and the patient can basically return to work. "Good" means that symptoms partially disappear, straight leg can be raised by more than 70°, muscle strength returns to normal, and the patient can return to normal work. "Very good" means symptoms and signs basically disappear but pain occasionally remains, straight leg can be raised by 50°, and the patient can do light work. "Good" means that pain and some signs are alleviated, straight leg can be raised by 30°, and the patient can perform activities of daily living (ADL) but cannot do any work. "Bad" means that symptoms and signs are unimproved or even aggravated. 5. Lumbago-evaluating scale stipulated by the orthopedic society of Japan: "Cure" means that the score of main symptoms, signs and ADL is 29. "Improvement" means that the score of main symptoms, signs and ADL is less than 9. 6. Guangdong provincial basic standard for diagnosing and treating common diseases: "Cure" means that pain in the waist and leg disappears, straight leg can be raised by more than 70°, and the patient can return to work. "Improvement" means that straight leg can be raised by more than 50°, pain in the waist and leg is al-

<table>
<thead>
<tr>
<th>Research</th>
<th>No Included study</th>
<th>Control (n/N)</th>
<th>Intervention (n/N)</th>
<th>RR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duhuojisheng Tang vs traction therapy</td>
<td>2</td>
<td>27/98</td>
<td>41/98</td>
<td>1.52 (1.04, 2.22)</td>
<td>0.03</td>
</tr>
<tr>
<td>Duhuojisheng Tang vs Western Medical treatment</td>
<td>4</td>
<td>22/248</td>
<td>111/224</td>
<td>4.49 (2.96, 6.81)</td>
<td>&lt;0.00001</td>
</tr>
<tr>
<td>Duhuojisheng Tang and traction vs traction</td>
<td>5</td>
<td>64/314</td>
<td>114/299</td>
<td>1.69 (1.30, 2.19)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Duhuojisheng Tang and Western Medical treatment vs Western medical treatment</td>
<td>6</td>
<td>60/301</td>
<td>177/281</td>
<td>2.78 (2.17, 3.56)</td>
<td>&lt;0.00001</td>
</tr>
<tr>
<td>Duhuojisheng Tang and acupuncture vs acupuncture</td>
<td>2</td>
<td>49/125</td>
<td>89/115</td>
<td>1.64 (1.30, 2.08)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Duhuojisheng Tang, traction and acupuncture vs traction and acupuncture</td>
<td>2</td>
<td>38/124</td>
<td>60/120</td>
<td>1.53 (1.11, 2.10)</td>
<td>0.009</td>
</tr>
<tr>
<td>Duhuojisheng Tang, traction and Western Medicine vs traction and Western Medicine</td>
<td>3</td>
<td>133/342</td>
<td>265/375</td>
<td>1.80 (1.56, 2.08)</td>
<td>&lt;0.00001</td>
</tr>
<tr>
<td>Duhuojisheng Tang, cupping and other therapy vs cupping and other therapy</td>
<td>2</td>
<td>26/100</td>
<td>5/57</td>
<td>2.97 (1.21, 7.31)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Notes: n: The number of the cases of symptoms improve; N: Sample size of treatment/control group; RR: relative risk.
leviated, and lumbar function is improved. "No cure" means that symptoms are unimproved or even aggravated.

**Evaluating quality of articles**

Deviation risks were evaluated according to the six standards for randomized controlled trials in the manual for systematic evaluators in Cochrane coordinative net. Computerized methods of random numbers was used in 7 of the 31 selected experiments, the lot-drawing method was used in 1 article, and the randomized method was not described in the remaining 23 experiments. None of the experiments mentioned random allocation or the use of the blind method. Study participant dropout was described in one study. None of the experiments reported incomplete results, and the rest of the evaluated items were unclearly described. All 31 selected articles were of low quality.

**Results of statistic analysis**

For the current study, VAS score was selected as the primary index, and improvement of clinical symptoms and adverse reaction were used as secondary indexes. VAS score: a 10 cm long line is drawn in a piece of paper. 0 at one end of the line expresses no pain, 10 at the other end expresses megalgia, and the section between 0 and 10 expresses pain to different extent. The patient is asked to draw a mark in the line according to his or her pain level. VAS is the scale most commonly used to measure pain; however, only four of the selected articles in this study described VAS score of patients; 1 of them depicted the difference in VAS score before and after treatment, as well as the P value, and the other three articles reported the P value without reporting VAS score. The four articles reported the difference in VAS score between the treatment group and the control group as P<0.05, and two of them reported P<0.01, indicating that Duhuojisheng Tang used alone or used together with other therapies has certain curative effects in alleviating pain.

Improvement of clinical symptoms: because the five therapies for prolapse of lumbar intervertebral disc used different standards for judging curative effects, it is difficult to unify the standard of obvious effects and improvement, but the standard of cure is comparably unified. To summarize the above-mentioned four standards for judging curative effects, "cure" means that pain in the waist and leg disappears, muscle strength returns to normal, straight leg can be raised by more than 70° and the patient can return to his/her original work.

As shown in Table 2, Duhuojisheng Tang, either used alone, together with another drug or with physical therapy, had a superior curative effect compared to the treatment in the control group, indicating that Duhuojisheng Tang is better at improving clinical symptoms and alleviating pain.

In addition, four experiments could not be analyzed comprehensively. One of them compared Duhuojisheng Tang and acupoint injection with traction and Western medical treatment [P<0.0001, RR=1.41, 95% CI (1.19,1.67)]. The second study compared Duhuojisheng Tang, hot application with dregs of decoction and traction with traction and Western medical treatment [P=0.001, RR=1.29, 95% CI (1.11,1.50)]; the curative effect of Duhuojisheng Tang was superior to that of the two control measures. The third study compared Duhuojisheng Tang with acupuncture, traction and Western medical treatment [P=0.05, RR=1.12, 95% CI (1.00,1.24)]. The fourth study compared Duhuojisheng Tang and massage with massage alone [P=0.09, RR=1.15, 95% CI (0.98,1.35)]; the curative effect of Duhuojisheng Tang was similar to that of the two control measures.

**Adverse reactions**

Four studies reported adverse reaction. Three studies reported that patients in the control group had a mild gastrointestinal reaction to the drug, which was alleviated after they discontinued use. The other study reported no obvious adverse reactions.

**DISCUSSION**

A systematic review of the literature was conducted to evaluate the curative effect and safety of Duhuojisheng Tang on lumbar intervertebral disc prolapse. This research involved 31 articles on randomized control experiments: 6 articles on solely using Duhuojisheng Tang to treat prolapse of lumbar intervertebral disc, 14 articles on using Duhuojisheng Tang and traction or using traction and another therapy, 5 articles on using Duhuojisheng Tang, acupuncture and massage, and 5 articles on using Duhuojisheng Tang and Western Medicine. In these 31 studies, prolapse of lumbar intervertebral disc was mainly treated with Duhuojisheng Tang, physical therapy and Western Medicine. Based on our analysis of these studies, Duhuojisheng Tang appears to have a certain curative effect of lightening pain and alleviating symptoms in the treatment of prolapse of lumbar intervertebral disc. Although intervention measures have been roughly classified, each therapy has its own features, and measures were appropriately modified according to each patient’s conditions. For example, points of acupuncture were not completely the same between patients. Therefore, there are few articles on completely identical therapies and intervention measures. Using such articles may influence the quality of evidence.

Twenty-seven of the selected articles had explicit inclusion and exclusion criteria. The majority of patients were diagnosed with prolapse of lumbar intervertebral disc by CT or MRI. Standard of diagnosis and standard for judging curative effect were relatively identical. These experiments mainly adopted the TCM standard of curative effect stipulated by the National TCM Administration or principle for clinically directing new
Chinese drugs. All experiments adopted the clinical effective rate as a comprehensive index to judge curative effect. Most articles reported simple baseline characteristics and carried out statistical tests. A unified method makes the results of statistic analysis more credible.

The selected articles have quite a few defects in methodology. Randomization is an important method for avoiding deviations in clinical research. Twenty-three of the 31 articles literally mentioned "random", and 8 articles reported randomized methods. The selected articles did not describe how to produce random order or how to randomly divide groups. Therefore, there may be false randomized researches. None of the articles reported information on hiding a randomized plan, on whether the blind method had been used, or on estimating sample size before the experiment. These defects bring some indeterminacy to experimental results.

As compared with other systematic summaries, retrieved were 14 articles on the treatment of prolapse of lumbar intervertebral disc with TCM and Western Medicine,4,6-11 4 articles on comparison of Western medical therapies,12-16 including injection of collagenase and surgery,17,18 10 articles on TCM therapies, including acupuncture,19,20 TCM manipulations,21 tiny needle-knife,22 fumigation with Chinese medicine,23 and TCM comprehensive therapy.24 In 10 articles, TCM treatment of lumbar intervertebral disc prolapse showed some superiority in improving symptoms and alleviating pain, but no definite conclusion had been drawn. It is still necessary to verify the results with large-size samples and high-quality randomized control experiments. Because there is no other systematic summary on using Duhuojisheng Tang to treat the condition, this systematic summary is of certain creativity.

In this study, we found that Duhuojisheng Tang used together with physical therapy and Western Medicine has a better curative effect than physical therapy and Western Medicine used alone for the treatment of prolapse of lumbar intervertebral disc. However, we do not suggest using Duhuojisheng Tang alone because traction is a mature and indispensable therapy for treatment of lumbar intervertebral disc prolapse. We suggest combined use of medicine in clinical practice. Clinical practitioners should strive to conduct high-quality clinical studies to provide evidence for rational and effective use of drugs.

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